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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,243	11/17/2006	Koji Odan	YAMAP1012US	4126

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,243	ODAN ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2/08;5/12/08;6/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are presented for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji et al. (WO 02/097107; cited in the IDS filed 6/6/06) in view of Motoo et al. (JP 11-298058 (full machine translation) and Suzaki et al (1983; cited in the IDS filed 12/2/08).

Fuji discloses a method for producing glucans comprising the steps of allowing a reaction solution coning sucrose, a primer, inorganic phosphate or glucose-1-phosphate (G1P), sucrose phosphorylase (SP) and alpha-l,4-glucan phosphorylase (GP) to react

to produce glucans (see abstract, paragraph 4, page 2 to paragraph 1, page 6 of the description and claim 1). The preferred concentration of the phosphate sources is 20-250mM (see paragraph 3, page 38 of the description). This range overlaps the claimed ranged of 1 mM to 50 mM of instant claim 10.

Fuji does not teach that that and alpha-1,4-glucan such as cellobiose or celloligosaccarhide is used instead of sucrose as the raw material for producing the intermediate G1P. Nor does Fuji disclose that cellobiose phosphorylase and cello dextrin phosphorlase are applied on beta-1,4-glucans instead of sucrose phosphorylase. Fuji does not teach the phosphoric source range of 1 to 50 mM.

It is commonly known in the prior art to obtain G1P from a beta-1,4-glucan by reaction with cellobiose phosphorylase (CBP). For example Motoo disclose that cello oiligosaccharides can be produced by converting soluble starch (amylose) by reaction with alpha-1,4-glucan phosphorylase (AG) to yield glucose and G1P. The G1P is then contacted with a glucose donor, cellobiose phosphorylase and cello dextrin phosphorylase to product cellobiose. CBP and cello dextrin phosphorylase act on a beta-1,4-glucan having a polymerization degree of 2 and on that having a polymerization degree of 3 or more, respectively, to produce G-1-P. Thr ordinary artisan would recognize that the reaction sequence taught by Motoo is the reverse of reacting a cello oligosaccharide of polymerization *n* and CBP and cello dextrin phosphorylase to give G1P and cello oligosaccharide of polymerization n-1 wherein the G1P product then reacts with alpha-1,4-glucan phosphorylase to give amylose, an alpha-1,4-glucan. Similarly, this is analogous to beginning with cellobiose reacting with CBP to give G1P

and glucose which reacts with a primer and AG to give amylose, a alpha-1,4-glucan. The ordinary artisan would have realized that the reverse reaction is the same as that employed by Fuji except that the substrate is cellobiose or cello oligosaccharide of polymerization *n* and the phosphorylase is CPB.

Suzaki discloses that starch can be prepared by separate conversion of cellulase to cellobiose, cellobiose to glucose-1-phosphate and G-1P to starch (an alpha-1,4-glucan; starch is amylose). The conversion of cellobiose to G-1-p takes places with cellobiose phosphorylase to produce G1P and glucose. The conversion of G1P to amylose occurs with an alpha-1,4,glucan phosphorylase and primer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute cellobiose or cello oligosaccharide of polymerization n and CBP and/or cello dextrin phosphorylase for sucrose and SP, respectively, to produce alpha-1,4-glucans. The ordinary artisan would have been motivated to do so since CBP, cellolodextrin phosphorylase, SP and GP are all phosphorylases that produce or use G1P in reversible reactions. Hence, using cellobiose-type substrates and enzyme is simply an obvious substitution to the same end product, starch (e.g., amylose). According to the MPEP 2143:

> B. Simple Substitution of One Known Element for Another To Obtain Predictable Results
>
> To reject a claim based on this rationale, Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:
>
> (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step,

element, etc.) with other components;

(2) a finding that the substituted components and their functions were known in the art;

(3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and

(4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that the substitution of one known element for another yields predictable results to one of ordinary skill in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

The ordinary artisan would have had a reasonable expectation that cellobiose and CPB or oligo cellobiose and CPB and cello dextrin phosphorylase could be substituted for sucrose and SP since Suzaki teaches that the reverse reaction taught by Fuji (e.g. cellobiose-type substrate and CPB) react in the forward direction to provide amylose.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to choose appropriate limitations on the concentration of the phosphate donor for the claimed reaction. One skilled in the art would be motivated to optimize reaction conditions to obtain an increased product yield. According to *In re* Aller 105 USPQ 233,

> Normally, change in temperature, concentration, or both, is not patentable modification; however such changes may impart patentability

> to process if ranges claimed produce new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed critical ranges, and applicant has burden of proving such criticality; even though applicants modification results in great improvement and utility over the prior art, it may still not be patentable if modification within capabilities of one skilled in art: more particularly, where general conditions of claim are disclosed in prior art, it is not inventive to discover optimum or workable ranges by routine experimentation.

Enzymatic phosphorylation and concentrations of substrates thereof are well known in the art. An ordinary skilled artisan would naturally experiment with the substrate concentrations for the exploitation of success. It is apparent that the claimed process is merely different in degree and not in kind from the reference process.

Accordingly, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to substitute cellobiose-type substrates and enzymes and to optimize the concentration of the phosphate donor substrate, especially in the absence of an objective showing of surprising or unexpected results.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji et al. (WO 02/097107; cited in the IDS filed 6/6/06) in view of Motoo et al. (JP 11-298058 (full machine translation) and Suzaki et al (1983; cited in the IDS filed 12/2/08), as applied to claims 1-4 and 9-11 above, and further in view of Kitaoka et al (2002; cited in the IDS filed 5/12/08) and Ota et al. (JP 10-099098; full machine translation).

The combined disclosures by Fuji, Motoo and Suzaki are discussed supra.

The combined disclosures do no teach removing glucose produced as a by products from the solution simultaneously with the production of the alpha-glucan by reaction with glucose oxidase, mutarotase and catalase.

Kitaoka teaches that CBP is inhibited by product inhibition due to the production of G1P and the byproduct, glucose (page 43, left column). The ordinary artisan would understand from this disclosure that inhibition of CBP will reduce the yield of the desired product.

Ota teaches that trehalose can be measured more accurately by combining trehalose phosphorylase (TP) with enzymes that eliminate the influence of the glucose byproduct as inhibitor of TP (abstract and Detailed Description). TP is combined with glucose oxidase, mutarotase and catalase to dispose of the glucose byproduct and prevent product inhibition of TP. The trio enzymes converts glucose into the glucose lactone which is not inhibitory to phosphorylase-type enzymes. Hence the co-generated beta-D-glucose produced by CBP can be detected quantitatively.

It would have been obvious to employ a system to eliminate the inhibition of CBP in the claimed reaction system to make amylose by adding an enzyme combination to change glucose into a molecule that does not inhbit CBP. The ordinary artisan would have been motivated to do so becasue elimination of glucose prevents product inhibition of CPB, thus, increasing the yield of the desired byproduct, amylose. The ordinary artisan would have had a reasonable expectation that the trio of enzymes would successfully eliminate unwanted glucose byproduct becasue Ota showed that

the enzyme trio successfully disposed of the inhibitory glucose in a similar phosphorylase reaction where glucose was known to inhibit the phosphorylase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651